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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/939,209 | 08/24/2001 | Pat Ressler Levitt | 00-539-US | 3394 |
| 7590 | 09/22/2004 | | EXAMINER | |
| Frederick H. Colen REED SMITH LLP P.O. Box 488 Pittsburgh, PA 15230-0488 | | | QIAN, CELINE X | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1636 | | |

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/939,209 | LEVITT ET AL. |
| Examiner | Art Unit | |
| Celine X Qian | 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 June 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1, 5, 18, 20 and 46 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 5, 18, 20 and 46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 January 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims 1, 5, 18, 20 and 46 are pending in the application.

This Office Action is in response to the Amendment filed on 6/21/04.

Response to Amendment

The objection to the specification has been withdrawn in light of Applicant's amendment of the claims.

The objection to claims 1-7, 20 and 40-43 has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 18 and 19 under 35 U.S.C.101 has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claim 3 under 35 U.S.C.112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

Claims 1, 5, 18, 20 and 46 are rejected under 35 U.S.C.112 1st paragraph (written description) for reasons set forth of the record mailed on 12/18/03 and further discussed below.

Claims 18 and 20 are rejected under 35 U.S.C.112 1st paragraph for reasons set forth of the record mailed on 12/18/03 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 18, 20 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue that the term “contiguous” means “connecting without a break.” As such, Applicants assert the recitation of “contiguous portion thereof” refers to only continuous fragments of SEQ ID NO:3-not fragments outside or adjacent to SEQ ID NO:3. Applicants thus conclude the written description requirement is met.

This argument has been fully considered but deemed unpersuasive. Claim 1 is drawn to an isolated DNA sequence comprising SEQ ID NO:3, wherein it comprises one of the recited variants. The term “contiguous portion thereof” refers to contiguous portion of SEQ ID NO:3, although without a break, it still encompasses sequences either 5’ or 3’ to the SEQ ID NO:3 since SEQ ID NO:3 is genomic DNA encoding RGS4 protein. Even if the contiguous portion is limited to the sequence within SEQ ID NO:3, the specification still fails to meet the written description requirement because the structural and functional relationship of such portion is not described in the instant specification. In other words, although the recited variants of SEQ ID NO:3 encodes a RGS4 protein that are linked to schizophrenia, it is unclear which portion, or the size of the portion of SEQ ID NO:3 are critical elements for such association. In addition, the specification also fails to describe any sequence that corresponds to SEQ ID NO:3. Moreover, the newly added claim 46 recites a DNA sequence that is complementary to the DNA sequence of claim 1. Complementary sequences to a DNA comprising SEQ ID NO:3 and portions thereof

encompass a large genus of oligonucleotides and nucleic acids of various sizes that may not related to schizophrenia at all. As such, the specification fails to describe a representative number of species by their complete structure or other identifying characteristics. Therefore, the written description requirement is not met.

Claims 18 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell transformed with an expression vector comprising SEQ ID NO:3, does not reasonably provide enablement for human or transgenic animals comprising SEQ ID NO:3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

In response to this rejection, Applicants argue that the instant amendment overcome the rejection.

The addition of the recitation of “wherein said expression system comprises a recombinant host cell transformed or transfected with said DNA sequence” does not overcome the rejection of the record because the claim still reads on a transgenic animal comprising recombinant DNA transfected into its cell. The rejection is maintained for same reason as discussed in the office action mailed on 12/18/03.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.


DAVE T. NGUYEN
PRIMARY EXAMINER